Medtronic

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URGENT: FIELD SAFETY NOTICE

CPFA Coupled Plasma Filtration Adsorption™ in Patients with Septic Shock

20 April 2018

Attention: Risk Management Director, Safety Officer, OR and ICU Materials Management, ICU Medical Directors

Dear Valued Customer:

The reason you are receiving this letter is that you are a current user of either the LYNDA™ or the Amplya Acute Multitherapeutic System™ and CPFA Coupled Plasma Filtration Adsorption™ therapy is a treatment that can be performed on these systems.

The purpose of this letter is to advise you of the early termination of the COMPACT-2 (COMbining Plasma-filtration and Adsorption Clinical Trial 2) clinical trial. On October 23, 2017, GiViTI, a not-for-profit research organization within the Mario Negri Research Institute, terminated the study early due to observed higher mortality rates in septic shock patients receiving CPFA therapy compared to patients receiving standard care.

The COMPACT-2 investigators are analyzing their data to better understand the reasons for the observed results and intend to publish the study results after their independent assessment is complete. All study sites have been notified by GiViTI of the study's early termination and their recommendation to not use CPFA for treating patients with septic shock. Pursuant to this recommendation from GiViTI and the extended timeline associated with the rigorous collection of patient data, Medtronic is informing all clinicians who might be using or contemplating the use of CPFA therapy for patients in septic shock that this treatment is **not** recommended.

As a result of the COMPACT-2 study findings in septic shock patients, Medtronic will add the following warning statement in CPFA User Manuals and Instructions for Use:

> **WARNING:** In a clinical study, higher early mortality (within 72 hours of randomization) was observed in septic shock patients receiving CPFA Coupled Plasma Filtration Adsorption™ therapy compared to patients receiving standard care. Septic shock patients often have clinical characteristics (hemodynamic instability, coagulation disorders) that increase the risk of extracorporeal treatment. Based on the preliminary data from this study, CPFA should not be used in patients with septic shock.

If results of the independent assessment being conducted by the COMPACT-2 investigators suggest that the observed early mortality can be attributed to specific patient conditions at the time of treatment or other factors, we will update the labeling accordingly. Until then, please inform your staff of this warning statement.

This Field Safety Notice is specific to the use of CPFA in septic shock patients. Medtronic has not received any reports suggesting potential harm in other patient indications for which the product is approved.

If you choose to return any unused CPFA product related to this notification, please complete the Product Return Form and ship to the address noted on that form. You may contact your Medtronic Representative for more information.

Thank you for your attention to this notification. We are committed to ensuring unsurpassed patient safety and customer service through transparent communication. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Diana Teo
Quality System Manager SEA
Medtronic

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Customer Confirmation Form
Field Safety Notice
CPFA Coupled Plasma Filtration Adsorption™ in Patients with Septic Shock

Customer Contact Details	Contact Details
Hospital / HCP:	**Name:**
	E-mail:
Address:	**Phone:**
Telephone no:	
Fax no:	
E-mail:	

If you have opted to return the unused affected inventory, please fill up the below table.

Please tick (either one) only:

☐ No, no affected inventory to be returned.

☐ Yes, unused affected inventory to be returned (Please fill up the below table if chosen)

Item code	Product Description	Lot number	QTY (Each)

I have read and understand the information provided and acknowledge receipt of the Field Safety Notice regarding CPFA Coupled Plasma Filtration Adsorption™ in patients with septic shock dated 19 April 2018 by signing below. I also agree to further distribute and communicate this important information within my facility as required.

Name: _____ (print) Signature: _____Stamp: _____ Date: _____